

Your Competent Partner for

Regulations & Guidelines governing Clinical Research and Drug Development

The FOCUS competence team located in Neuss

- has expertise and experience in clinical trial submissions to EU and non-EU authorities, clinical supply handling, and a track record of successful GxP Audits
- operates in compliance with pertinent guidelines and regulations such as ICH GCP, the EU CT Directive (2001/20/EC), EU Guide to GMP with Annex 13, the German Drug Law, the German GCP Ordinance and other local or country-specific guidelines and regulations as required
- is part of FOCUS Development Group which was one of the first CROs in Germany to achieve ISO 9001 certification through Lloyd's Register QA Ltd. in 1995

Regulatory Document Preparation and Authority Contacts

The competence team

- has extensive experience with regulatory authorities with respect to CTAs, Scientific Advise procedures, Orphan Drug designations, and GxP authorities, like EMEA/German BfArM, Russian MoH, Serbian Authorities, US-FDA, Brazilian Sanitary Surveillance Agency (BSSA).
- offers consultancy and preparation of documents in close cooperation with our clinical research and pharmaceutical experts.
- manages import and export documentation of clinical trial supplies as well as CTS handling according to GMP.

The Competence Team can offer you the benefit of:

Pharmacy with Manufacturing License and Qualified Person (QP)

Our pharmacy has a valid manufacturing license from the local authority since 1992 and is able to release study medication after the final manufacturing step.

We have imported investigational medicinal products from third countries like India, Japan, USA and Switzerland successfully into the European Union.

Our pharmacy supports 30 – 50 clinical trials per year.

Feasibility Checks and Clinical Trial Supply Handling Services

- Study/Protocol Feasibility Check according to FOCUS manufacturing/import license and local laws
- Familiarisation with protocol and dosing scheme
- Handling of Clinical Trial Supplies (receipt/return, shipping, storage of retention samples)
- Distribution to investigator/study site
- Storage under controlled and secured conditions
- Drug accountability
- Documentation

GMP Manufacture, Quality Control and Release of Investigational Medicinal Products (IMP)

- cGMP Manufacturing Review
- Packaging & labelling
- Decanting/dividing up
- Oral solution
- Filling of capsules
- Reconstitution
- Batch release

Management of Contract Manufacturers and Supervision of Activities

- Import/export of Clinical Trial Supplies from non-EU countries
- GMP audits of international manufacturing sites (e. g. Japan, India)
- Certified destruction of Clinical Trial Supplies

Regulatory Affairs (RA)

FOCUS RA has many years of hands-on experience with Clinical Trial Applications and their reviewers. Missing data, especially in the CMC documentation, is by far the most important and frequent reason for Competent Authorities to raise objections. The preparation and/or country specific review of CTAs by our experts secures that such gaps are avoided and thus, this service can add great value to your project.

FOCUS RA managed and conducted a number of Scientific Advice meetings with the German Authorities and the EMEA. Furthermore, RA received Orphan Drug Status from EMEA for some compounds.

Well prepared comprehensive and complete documentation is crucial when dealing with authorities.

Finally, FOCUS RA supports EU clinical trials for sponsors residing outside the EU.

- Regulatory Road Map/Strategy
- Advice on Drug Development and Regulatory Compliance
- Orphan Drug Application
- Scientific Advice
- Clinical Trial Application (Europe including Eastern Europe (Russia, Serbia, Czech Republic)) (Pre-) IND Application
- Review & Preparation of Regulatory Dossiers/Documents (Modules 2 – 5 in CTD format, IMPD, ASMF, IB)
- Regulatory Due Diligence
- EU Legal service

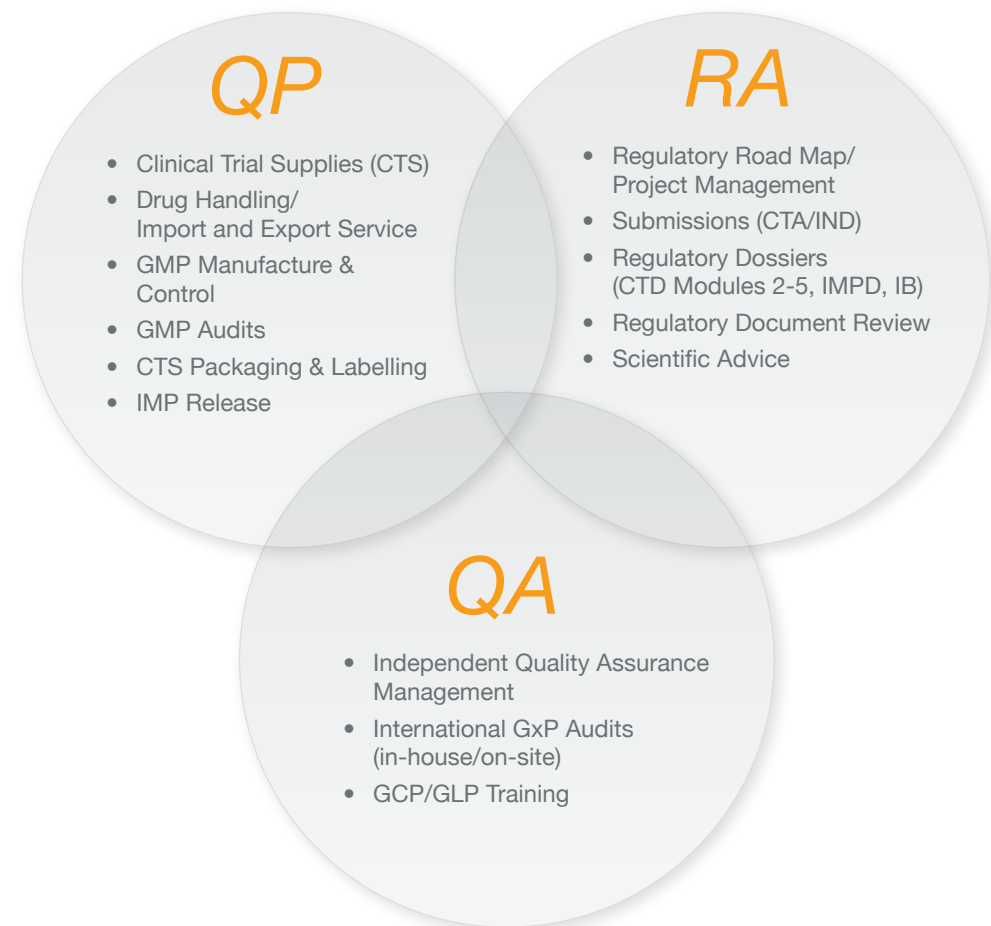
Quality Assurance (QA)

Our auditors have over 20 years of experience in QA auditing, US-FDA inspections and performing GCP/GLP training. They have conducted numerous on-site and in-house audits in Western Europe, Central- and Eastern Europe, including Russia and Ukraine as well as in Africa and Asia. QA has played a major role in helping FOCUS to achieve ISO 9001 certification in May 1995 and GLP certification for FOCUS Bioanalytical Laboratory in Neuss, Germany, in 1993 as well as the FOCUS Immunology Laboratory in Heidelberg, Germany, in 2009.

- Consultancy with respect to preparing for and the conduct of Regulatory Authority Inspections
- Conduct of different types of GxP audits, e.g. audit of Phase I to IV Clinical Studies to assess compliance with GxP Guidelines and Regulations (Europe (including Eastern-Europe) Asia, Africa)
- In-house and on-site audits
- Audits of essential documents (protocols, reports, CRF, ICF, IB etc.)
- GCP/GLP training

FOCUS addresses and resolves the often intimately linked critical points in Regulatory Affairs and Quality Processes by an integrated expert team.

This **Competence Team** offers you the benefit of an **experienced Regulatory Affairs (RA)/Qualified Person (QP)/Quality Assurance (QA)** team under one roof in a state-of-the art development facility in Neuss/Düsseldorf, Germany.



For more information please contact:

The FOCUS Experts and Department Heads

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FOCUS on Regulatory Affairs and Expertise in GMP, GLP and GCP

